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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,866	08/07/2002	Erling Sundrchagen	7885.81USWO	8079

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EXAMINER

ZEMAN, MARY K

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,866

Applicant(s)

SUNDREHAGEN, ERLING

Examiner

Mary K. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2004 and 22 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 28-55 are pending in this application. The sequence related amendments and sequence listing of 12/22/04 have been entered.

Applicant's arguments filed 8/24/2004 have been fully considered but they are not completely persuasive.

Claims 28-55 remain rejected under 35 U.S.C. 102(b) as being anticipated by Nakayama (WO 99/13332, US Equivalent 6,432,632 B1) for the reasons set forth below, and of record.

Applicant argues that Nakayama does not provide for methods wherein the binders are of low molecular weight, specifically below 5000. Applicant's arguments have been fully considered but are not persuasive. Nakayama specifically contemplates the use of low molecular weight binders at column 7 lines 18-25. "the peptide as biological substance refers to those having a molecular weight of less than about 1000. the protein as a biological substance refers those having a molecular weight of about 1000 or more. While Nakayama et al is largely directed to high molecular weight complexes, the teachings therein specifically include the use of low molecular weight compounds. Nakayama also discloses the same compositions in kits. As such, Nakayama remains anticipatory.

As set forth previously, The claims are drawn to methods of determining the concentration of an analyte in a test sample, wherein a fluorescence polarization method is used to detect binding between the labeled reagent and the analyte. The method takes place in a single stage, with no washing steps or multiple additions of reagents. The sample can be any biological fluid such as blood. The binding agent can be a low molecular weight aptamer or binder, an antibody or fragment thereof. The assay can be for a single analyte, or multiple analytes. The fluorescence label has an absorption above 640nm. The reagent can comprise lysing reagents or anti-coagulants. The label can be one of any number of dyes including Texas Red, Cy5, or one of the Biodypi reagents, and is covalently linked to the binding agent. The assay can be measured as a function of time. Standard curves, temperature compensation etc can be used and stored in the polarization instrument being used. The method can be used to determine the concentrations of clinically related substances. Reagents and kits comprising the reagents are also claimed. It is noted that the kits merely require the reagent in a container.

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Nakayama et al. (WO 99/13332 A1 3/18/99) was published more than a year before the priority document was filed. The WO document is not in English. US 6,432,632 is the US National Stage patent, which resulted from the WO document, and is a proper English Language equivalent. All references to column and line number are to the US Patent document.

The binding partner of Nakayama is specifically fluorescently labeled, with a dye such as rhodamine, that has absorption and emission within the claimed parameters. The labeled binding reagent is mixed with the biological sample, and the change in the fluorescence polarization is determined without further washing, adsorbing or detecting steps. (abstract) The binding reagent may be an antibody capable of binding a peptide, or a peptide capable of binding an antibody. (column 2 lines 1-65) C-reactive protein is specifically contemplated. (col 2 line 34-35) Fluorescent dyes specifically contemplated include rhodamine, cyanin, pyrene, etc. (col 5 lines 60-65). The sample may be any type of biological fluid such as blood. (col. 6 lines 65-67) Standard curves and temperature corrections can be prepared ahead of time and stored. (see examples) The methods of Nakayama can be used to determine the concentration of clinically relevant molecules in samples from living organisms. Nakayama discloses the reagents and kits comprising the reagents. As such, Nakayama meets the limitations of the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on (571) 272 0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


MARY K. ZEMAN
PRIMARY EXAMINER
